Proposed Re-evaluation Decision PRVD2010-05

Butoxypolypropylene Glycol

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the insect repellent butoxypolypropylene glycol, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration for the sale and use of products containing butoxypolypropylene glycol in Canada.

An evaluation of available scientific information found that products containing butoxypolypropylene glycol do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of butoxypolypropylene glycol uses, new risk-reduction measures must be included on the labels of all products. No additional data are being requested at this time.

It should be noted that for end-use products containing more than one active ingredient under re-evaluation, registration status might change as a result of the re-evaluation of the remaining affected active ingredients.

This proposal affects all end-use products containing butoxypolypropylene glycol registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for butoxypolypropylene glycol and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of butoxypolypropylene glycol.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Butoxypolypropylene glycol, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in the 2007 RED, the USEPA concluded that butoxypolypropylene glycol was eligible for reregistration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in this RED were an adequate basis for the proposed Canadian re-evaluation decision.

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

What Is Butoxypolypropylene Glycol?

Butoxypolypropylene glycol is an insect repellent that is used to control flies, mosquitoes and gnats on race horses and on horses/ponies used for recreation. Butoxypolypropylene glycol is applied by wiping-on with a cloth or spraying on with a trigger pump sprayer.

Health Considerations

Can Approved Uses of Butoxypolypropylene Glycol Affect Human Health?

Butoxypolypropylene glycol is unlikely to affect your health when used according to the revised label directions.

People may be exposed to butoxypolypropylene glycol while preparing and/or applying the pesticide to horses and/or ponies, or while handling treated animals (for example, grooming).

The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that butoxypolypropylene glycol was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Environmental Considerations

What Happens When Butoxypolypropylene Glycol Is Introduced Into the Environment?

Butoxypolypropylene glycol is unlikely to affect non-target organisms when used according to the revised label directions.

Birds and aquatic organisms could be exposed to butoxypolypropylene glycol in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. In this screening-level assessment, the resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas, a risk quotient greater than the level of concern indicates some potential risks of concern.

The USEPA concluded that the reregistration of butoxypolypropylene glycol was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of butoxypolypropylene glycol, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- Additional advisory label statements to reduce user and bystander exposure
- Clarification of the statement regarding the use of treated animals for food/feed

Environment

- Additional advisory label statements to reduce potential surface water contamination

Next Steps

Before making a final re-evaluation decision on butoxypolypropylene glycol, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] document that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Butoxypolypropylene glycol is an insect repellent that is used on horses and ponies.

Following the re-evaluation announcement for butoxypolypropylene glycol, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the labels of domestic class end-use products in Canada.

The Pest Management Regulatory Agency (PMRA) used recent assessments of butoxypolypropylene glycol from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) document for *Polypropylene glycol*, dated 25 September 2007, as well as other information on the regulatory status of butoxypolypropylene glycol in the United States which can be found on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name:	Butoxypolypropylene glycol
Function:	Insect repellent
Chemical family:	Polypropylene glycol
Chemical names:	
International Union of Pure and Applied Chemistry:	ά-butyl-ω-hydroxy-poly-oxy(methyl-1,2-ethanediyl)
Chemical Abstracts Service:	1-(1-butoxypropan-2-yloxy)propan-2-ol
Chemical Abstracts Service Registry Number:	9003-13-8
Molecular formula:	$(C_3H_6O)_nC_4H_{10}O$
Structural formula:	$RO—[CH_2\underset{\displaystyle CH_3}{\underset{\vert}{C}}HO]_n\,[CH_2CH_2O]_m—H$
Molecular weight:	1119.58 atomic mass units

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure	2.81×10^{-27} mm Hg
Solubility in water	0.19 µg/L
***n*-Octanol–water partition coefficient**	Log $K_{ow} \geq 3.42$

2.3 Comparison of Use Patterns in Canada and the United States

Butoxypolypropylene glycol is an insect repellent that is applied to horses and ponies to control flies, mosquitoes and gnats. Domestic class end-use products are formulated as an emulsifiable concentrate, a solution and as ready-to-use sprays. They are applied by wiping-on with a cloth or spraying on with a trigger pump sprayer. Typically, this chemical would be reapplied weekly, from May to October.

The American and Canadian use patterns were compared. The Canadian formulation types and the use as an insect repellent on horses and ponies are among those registered in the United States. In addition to horses and ponies, American use sites for this active ingredient include agricultural/farm premises, commercial animal kennels and sleeping quarters, dogs, cats, and pet living and sleeping quarters. Based on this comparison of use patterns, it was concluded that the USEPA RED for butoxypolypropylene glycol is an adequate basis for the re-evaluation of uses of this active ingredient in Canada.

All current uses are being supported by the registrants and were, therefore, considered in the re-evaluation of butoxypolypropylene glycol. Appendix I lists all butoxypolypropylene glycol products that are registered as of 3 January 2010, under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In their 2007 RED, the USEPA concluded that the end-use products formulated with butoxypolypropylene glycol met the safety standard under the American *Federal Insecticide, Fungicide and Rodenticide Act* and would not pose unreasonable risks or adverse effects to humans and the environment if used according to the amended product labels.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

In Canada, exposure to butoxypolypropylene glycol may occur while diluting or applying the pesticide to horses or ponies. Postapplication exposure to bystanders may occur while handling treated animals (for example, grooming).

When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). The toxicological endpoints used by the USEPA in the assessment of risk to human health are summarized in Appendix II.

3.1.1 Occupational Exposure and Risk Assessment

There are no commercial class products containing butoxypolypropylene glycol registered in Canada. Therefore, occupational exposure is not expected.

3.1.2 Non-Occupational Exposure and Risk Assessment

Residential risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating safety factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

3.1.2.1 Residential Handler Exposure and Risk

Among the exposure scenarios assessed by the USEPA, the following were considered relevant to the Canadian situation:

- diluting and/or applying liquids with a sponge;
- applying ready-to-use formulations with impregnated wipes; and
- applying ready-to-use formulations with trigger-pump sprayers

User exposure analyses were performed using generic surrogate exposure data. The endpoints selected for dermal and inhalation exposures were based on the same study; thus, the USEPA assessed the combined risk from exposure to butoxypolypropylene glycol through these routes. The assessments were based on the assumptions of 26 applications per year, at the maximum American rate.

Results indicated that residential handler exposure is not of concern, as the reported MOEs for adult short- and intermediate-term dermal and inhalation exposures were well above the target MOE of 100. In Canada, the maximum application rate on horses and ponies is slightly higher than the assessed American rate. However, the calculated MOEs provide sufficient protection to account for the difference between the American and Canadian rates. Further, the American use pattern is more extensive than in Canada (See Section 2.3).

The RED adequately addressed the potential exposure scenarios associated with the uses of products containing butoxypolypropylene glycol in Canada. Based on PMRA general practices, an advisory label statement is required on the labels of products that can be applied as sprays to minimize user and bystander exposure to this chemical. The proposed label amendments are listed in Appendix III.

3.1.2.2 Residential Postapplication Exposure and Risk

It was determined that potential postapplication exposure to adults via the inhalation route is not likely, based on the negligible vapour pressure of butoxypolypropylene glycol.

Exposure of children to this active through contact with treated pets (dogs and cats) was expected to result in higher dermal and incidental oral (hand-to-mouth) exposures than coming into contact with treated horses. Thus, this scenario was considered to be the worst-case residential postapplication exposure scenario by the USEPA. The reported MOE for this scenario was above the target MOE of 100. Based on this, the USEPA concluded that residential postapplication exposure is not of concern. In Canada, only adult postapplication dermal exposure is expected, based on the use pattern. The calculated MOE for the children-hugging pet scenario provides sufficient protection for adult short-term postapplication dermal exposure in Canada.

The RED adequately addressed the potential postapplication exposure scenarios associated with the use of products containing butoxypolypropylene glycol in Canada, and the conclusions apply to the Canadian situation. The PMRA does not propose additional risk-reduction measures with respect to postapplication exposure.

3.1.2.3 Exposure from Food and Drinking Water

Exposure from consumption of food is not expected for butoxypolypropylene glycol when used as directed. For consistency, the statement prohibiting use of treated animals for food/feed should be updated (see Appendix III).

Outdoor application to horses and ponies may lead to contamination of drinking water due to transfer of product from the animal to surface waters (for example, wash-off by precipitation or direct contact with water). Butoxypolypropylene glycol is expected to bind to soil. On this basis, it has the potential for runoff/erosion to surface water (see Section 3.2.1 for more details).

Environmental fate data was not available for butoxypolypropylene glycol; therefore, the estimated drinking water concentration used in the acute and chronic drinking water risk assessment were based in the chemical's limit of solubility (0.193 ppb), estimated with the Estimation Program Interface suite. The risk assessments were performed using the Dietary Exposure Evaluation Model with the Food Commodity Intake Database, incorporating food consumption data from the United States Department of Agriculture Continuing Surveys of Food Intakes by Individuals from 1994-96 and 1998.

A route-specific study was unavailable, therefore, the acute reference dose (aRfD) and chronic reference dose (cRfD) were based on an oral-equivalent no observed adverse effect level (NOAEL) of 120 mg a.i./kg bw/day. This endpoint was calculated based on the NOAEL of 1000 mg a.i./kg bw/day from a 90-day dermal rat study and a 12% bioavailability factor. An uncertainty factor of 100 was used in these assessments, therefore, the aRfD and cRfD were estimated to be 1.2 mg a.i./kg bw/day.

Both acute and chronic exposures from the consumption of drinking water for all populations subgroups were below the aRfD and cRfD. The highest exposure was found for infants less than one year old, at less than 0.1% of the aRfD and cRfD. It was, therefore, concluded that exposure to butoxypolypropylene glycol from the consumption of drinking water is not of concern.

Overall, the American use pattern encompasses the Canadian use pattern, and conclusions derived from the RED apply to Canada. Based on the potential for this chemical to enter surface water, the PMRA requires additional advisory label statements to further protect drinking water from contamination.

The advisory label statements proposed by the PMRA are listed in Appendix III

3.1.2.4 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to butoxypolypropylene glycol (for example, from drinking water and residential exposures).

In the RED, short-term aggregate risk assessments were conducted for children and adults. Application of a liquid formulation containing butoxypolypropylene glycol with a sponge was used to estimate the dermal and inhalation exposure contribution to the aggregate risk because this scenario was demonstrated to have the highest exposure for both routes. Exposure of adults to butoxypolypropylene glycol through drinking water and from handling and postapplication activites were aggregated. For children aged 0-5 years, exposure through drinking water and from contact with treated pets was assessed. In both groups, the margins of exposure exceeded the target of 100, therefore, aggregate exposure to this chemical is not of concern.

In Canada, the MOE estimated for aggregate exposures provides sufficient protection to account for the slight difference between American and Canadian application rates, and the conclusions derived from the RED are applicable to the Canadian situation. No additional mitigation measures with respect to aggregate exposure are required by the PMRA.

3.1.3 Cumulative Effects

The USEPA has not determined whether butoxypolypropylene glycol has a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Therefore, it was assumed that butoxypolypropylene glycol does not share a common mechanism of toxicity with other substances, and a cumulative risk assessment was not required.

3.2 Environment

3.2.1 Environmental Risk Assessment

The USEPA used Quantitative Structure Activity Relationship modelling and Estimation Program Interface Suite to determine the physical, chemical and environmental fate properties of butoxypolypropylene glycol. It was predicted that this chemical is stable, has a low potential to volatilize, is expected to bind to organic matter in soil and is unlikely to bioconcentrate to an appreciable degree. Metabolites of this chemical are not expected due to low biodegredation rates. Since butoxypolypropylene glycol is expected to bind to organic matter in soils, outdoor application to horses or ponies could potentially lead to this active ingredient reaching surface water through runoff and/or erosion.

The PMRA searched the available Canadian water monitoring data for detections of butoxypolypropylene glycol. This chemical was not monitored in the water monitoring database; therefore it is unclear as to whether butoxypolypropylene glycol is present in Canadian water sources.

To assess the ecological risk of butoxypolypropylene glycol to non-target organisms, the USEPA used a combination of data and modelling to estimate screening-level risk quotients (RQs). The RQs are based on the most sensitive toxicological endpoints and expected environmental concentrations (EECs). The estimated RQs were compared to corresponding levels of concern (LOCs). The Ecological Structure-Activity Relationships model was used to predict effects endpoints for organisms for which no data were received (chronic freshwater and estuarine/marine fish, chronic freshwater invertebrates, acute and chronic estuarine/marine invertebrates, and aquatic plants).

Butoxypolypropylene glycol was predicted to be practically non toxic to birds, slightly toxic to freshwater fish, freshwater invertebrates and estuarine/marine fish, and moderately toxic to estuarine/marine invertebrates on an acute basis.

Aquatic species:
The USEPA estimated conservative aquatic EECs for a standard farm pond, using the following assumptions:

- a maximum yearly application rate/hectare of 1.21 kg a.i./ha/year, based on the maximum application rate (18.6 g a.i./horse), 26 applications/year and an average of 2.5 horses/ha;
- all of the chemical was washed off the treated animals and reached the pond; and
- all of the washed off chemical exists in water at orders of magnitude above the estimated solubility limit of butoxypolypropylene glycol and that concentration in water is unaffected by potential partitioning of this chemical into the sediment.

Generated acute RQs did not exceed the LOC for freshwater fish and invertebrates or estuarine/marine fish. Chronic RQs did not exceed the LOC for freshwater fish and invertebrates or estuarine/marine fish. The acute RQ (RQ=0.15) exceeded the acute LOC of 0.05 and the chronic RQ (RQ=1.6) exceeded the chronic LOC of 1 for estuarine/marine invertebrates.

Although the LOCs for estuarine and marine invertebrates were exceeded, these findings are extremely conservative because of the assumptions made by the USEPA in their screening-level ecological–risk estimation (see above). Consequently, the USEPA concluded that the risks to estuarine and marine invertebrates are not of concern.

Birds:
The USEPA's screening-level risk assessment for birds used a modified mass per unit area calculation, similar to exposures for LD_{50}/ft^2 approach commonly used to assess exposure from granular formulations and seed treatments to non-target birds. The USEPA used the Terrestrial Exposure Model to calculate the lethal dose to 50% (LD_{50}) for different sizes of birds.

The acute RQs for 20-gram birds (RQ<9) and for 100-gram birds (RQ<1.4) exceeded the acute LOC of 0.5. The acute RQ for 1000-gram birds did not exceed the LOC. Chronic exposure was not expected due to the limited duration of exposure of birds to butoxypolypropylene glycol (from elimination of arthropods, assuming that the pesticide is effective, and from washing off of active).

Although the LOCs for small- and medium-sized birds were exceeded, the USEPA reported that there was considerable uncertainty regarding the extent of exposure to the chemical and the toxic effects from butoxypolypropylene glycol used in the calculation of the RQs. The USEPA assumed that the entire mass of the active applied to a horse or pony was bioavailable to birds consuming arthropod pests on the animal. They determined, however, that it was more likely that birds would only ingest butoxypolypropylene glycol incidentally applied to the arthropod pests, due to the very large molecular size of butoxypolypropylene glycol and its low vapour pressure. The estimated amount of available chemical on insects is below the dietary toxicity endpoint for birds. When compared, it was determined that the dietary route was of minimal significance for birds periodically feeding on the arthropod pests on treated livestock. The USEPA concluded that risk to birds from exposure to butoxypolypropylene glycol was not of concern.

The Canadian use pattern is encompassed by the USEPA's assessment. Although the Canadian maximum application rate is higher than the assessed American rate, the conclusions apply to the Canadian situation because the US assessment was considered to be highly conservative, thus overestimating the risk to non-target organisms (birds, aquatic species). The PMRA concluded that risk should not exceed the level of concern for non-target organisms exposed to butoxypolypropylene glycol from treated horses or ponies. However, based on general practices, the PMRA proposes additional advisory label statements on all end-use products to further protect the environment. Proposed label amendments are listed in Appendix III.

3.3 Pest Control Product Policy Considerations

3.3.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy, that is, Canadian Environmental Protection Act-toxic or equivalent, predominantly anthropogenic, persistent and bioaccumulative).

During the re-evaluation, butoxypolypropylene glycol was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, and evaluated against the Track 1 criteria for persistence and bioaccumulation. In order for butoxypolypropylene glycol or its transformation products to meet Track 1 criteria, the criteria for both bioaccumulation and persistence (in one media) must be met.

The log n-octanol-water partition coefficient (log K_{ow}) of butoxypolypropylene glycol is estimated to be 3.42, which is below the TSMP Track 1 cut-off criterion for log K_{ow} of 5.0. Additionally, the bioconcentration factor for this chemical is 86, which is below the TSMP Track1 cut-off criterion of 5000. Further, volatilisation is not an important route of dissipation and long-range transport is unlikely based on vapour pressure. On this basis, it is concluded that the use of butoxypolypropylene glycol is not expected to result in the entry of Track 1 substances into the environment.

3.3.2 Contaminants and Formulants of Health or Environmental Concern

During re-evaluation, contaminants in the technical grade active ingredient are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*. The list is used as described in the PMRA Notice of Intent NOI2005-01, and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the Canadian *Environmental Protection Act* (substances designated under the Montreal Protocol).

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02

4.0 Incident Reports

Starting 26 April, 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA.

As of 3 January, 2010, five incident reports have been submitted for products containing butoxypolypropylene glycol. All five incidents occurred in the United States and three of them involved uses that are not registered in Canada.

5.0 OECD Status of Butoxypolypropylene Glycol

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 30 member countries and provides governments with a setting in which to discuss, and develop economic and social policies to allow for consistency in practices across nations.

Current available information on the status of butoxypolypropylene glycol in other OECD member countries, suggests that it was assessed only in the United States, where all uses of butoxypolypropylene glycol were reviewed in 2007. The conclusions of the 2007 RED are the basis on which this re-evaluation was conducted and are summarized in this document.

6.0 Proposed Re-evaluation Decision

The PMRA has determined that butoxypolypropylene glycol is acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and the environment. The labels of Canadian end-use product must be amended to include the label statements listed in Appendix III. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision. No additional data are being requested at this time.

Butoxypolypropylene glycol end-use products that contain more than one active ingredient under re-evaluation will be eligible for continued registration only when all of those other active ingredients are determined to be eligible.

7.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and DACO tables can be found on our website at www.healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document for Polypropylene Glycol is available on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

List of Abbreviations

µg	microgram
a.i.	active ingredient
aRfD	acute reference dose
bw	body weight
cRfD	chronic reference dose
EEC	expected environmental concentration [also estimated environmental concentration]
g	gram(s)
ha	hectare
kg	kilogram
K_{ow}	*n*-octanol–water partition coefficient
f^2	foot squared
L	litre(s)
LD_{50}	lethal dose to 50%
LOC	level of concern
mg	milligram
mm Hg	millimetre mercury
MOE	margin of exposure
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PMRA	Pest Management Regulatory Agency
ppb	part per billion
RED	Reregistration Eligibility Decision
RQ	risk quotient
SF	safety factor
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
USEPA	United States Environmental Protection Agency

Appendix I Registered Products Containing Butoxypolypropylene Glycol as of 3 January, 2010

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
23778	Technical Product	Bayer CropScience, Inc.	Stabilene Fly Repellent	Liquid	100
10375	Domestic End-Use Product	Farnam Companies, Inc.	WIPE Liquid Wipe-On Fly Repellent	Solution	20
13850	Domestic End-Use Product	W. F. Young, Inc.	Absorbine Supershield Fly Repellent and Insecticide	Solution	10
21935	Domestic End-Use Product	W. F. Young, Inc.	Absorbine Supershield II Fly Repellent and Insecticide Solution	Solution	10
24411	Domestic End-Use Product	W. F. Young, Inc.	Absorbine Concentrated Fly Repellent	Solution	11.6

Appendix II Toxicological Endpoints for Butoxypolypropylene Glycol Health Risk Assessments

Exposure Scenario	Dose (mg a.i./kg bw/day)	Study	UF/SF/target MOE
Dietary - acute (drinking water)	oral equivalent NOAEL = 120 aRfD = 1.2	No appropriate endpoint attributable to a single exposure (dose) was identified; oral LD_{50} > 5000 mg/kg. Therefore, the USEPA used the short-term incidental oral endpoint (NOAEL of 120 mg a.i./kg bw/day).	100*
Dietary - chronic (drinking water)	oral equivalent NOAEL = 120 cRfD = 1.2	90-day dermal toxicity study in rat, LOAEL = 4000 mg a.i./kg bw/day, based on reduced body weight gain and changes in haematological parameters.	100*
Incidental oral - short/ intermediate-term	oral equivalent NOAEL = 120		100*
Dermal - short/ intermediate-term	NOAEL = 1000		100*
Inhalation - short/ intermediate-term	oral equivalent NOAEL = 120		100*

*(10x for interspecies variation and 10x for intraspecies variation)

Appendix III Label Amendments for Products Containing Butoxypolypropylene Glycol

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

The labels of end-use products in Canada must be amended to include the following statements to further protect human health and the environment.

I) The following statements must be included in a section titled **ENVIRONMENTAL HAZARDS**:

Avoid application when heavy rain is forecast.

II) The following statements must be included in a section titled **DIRECTIONS FOR USE**:

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

DO NOT use this product to horses/ponies destined for slaughter.

III) For Registration Number 10375, the following must be removed from the section of the product label titled **PRECAUTIONS**:

"Do not use on any animal being kept for milk, meat or egg."

IV) For products that are applied as a spray, the following statements should be included in the section titled **PRECAUTIONS**:

Only spray in a well-ventilated area.

References

Studies considered in the Chemistry Assessment

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

PMRA Document Number	Reference
1661580	Chemistry data used to support a Technical class product. Various Correspondence BPG-UCN-5, DACO: 2.99, DACO 2.11.3